

REMARKS/ARGUMENTS

In response to the Restriction Requirement dated June 18, 2004, Applicants elected to prosecute the claims of Group III. As the P.T.O. noted, the claims associated with Group III are Claims 60, 65-66, and 81-83. Claims 69-80 are cancelled without prejudice to subsequent revival.

In a previous response to a restriction requirement dated March 10, 2004, Applicants elected to prosecute claims directed to methods of sialylating a glycoprotein using a bacterial enzyme, *i.e.*, a generic claim. Dependent claims recited specific bacterial sialyltransferases. According to the present Restriction Requirement, use of different enzymes in a generic claim requires restriction of the subject matter of the claim.

By way of response, applicants provisionally elect to prosecute the claims of Group III (Claims 60, 65-66, and 81-83), with traverse. Applicants assert that claim 60 is a proper generic claim, and thus, Applicants further provisionally elect, with traverse, the method of claim 60 using a sialyltransferase from *C. jejuni*.

Under the controlling legal standard, restriction under 35 U.S.C. § 121 of the subject matter of a single claim is improper and impermissible. The Court of Customs and Patent Appeals extensively discussed and decided this issue in *In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328 (C. C. P. A., 1978) ("*Weber*"). In that case, the Court stated that

[a]s general proposition, an applicant has the right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant to eventually have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim...

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be “independent and distinct.” It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular *claim* on the same basis.

Id. at 331-332 (emphasis in the original). The same court also held that refusal to act on a claim in restriction practice in fact amounts to a rejection in *In re Haas*, 179 U.S.P.Q. 623, 625 (C.C.P.A. 1973). As the foregoing excerpt from *Weber* explains, § 121 does not provide a basis for rejecting a particular claim. *See Weber* at 332. Accordingly, § 121 does not empower the P.T.O. to refuse to examine a single claim on the merits simply because the P.T.O. asserts that the claim is drawn to independent and distinct inventions. Rather, the “basic right of the applicant to claim his invention as he chooses” under § 112 is “paramount” over the P.T.O.’s right to control “such administrative matters as examiner caseloads and amount of searching done per filing fee.” *See Weber* at 332.

Restriction of the subject matter of a single claim is improper for several reasons. To begin with, restriction within a single claim amounts to a rejection on the basis of 35 U.S.C. § 121 as specifically forbidden by *Weber* and *Haas*. These cases unambiguously and authoritatively hold that § 121 simply does not empower the P.T.O. to refuse to consider a single claim on the grounds that it is drawn to independent and distinct inventions. Thus, refusal to consider each of Claim 60 as filed constitutes an improper rejection on the basis of § 121 in direct contravention of the settled law.

Under the standard of *Weber*, Applicants have the right to have each claim examined on the merits. Restriction within, for example, Claim 60 and concomitant dispersal of the claimed subject matter to separate claims ends the investigation of patentability of Claim 60 before it begins. To be patentable, a claim must satisfy the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. As discussed above, there is no basis for rejecting a claim under § 121. *See Weber* at 332. If the subject matter of Claim 60 is dispersed to multiple fragmentary claims, then it will never be determined whether Claim 60 comports with §§ 101, 102, 103, and 112 and is

otherwise patentable. Thus, restriction within a single claim denies Applicants their right to have each claim considered on the merits.

Restriction within any claim 60 to a single species, each reciting a particular bacterial sialyltransferase, also does not allow Applicants to claim their invention as they define it under 35 U.S.C. § 112. While restriction of a number of claims to different applications does not affect this right, restriction within a claim vitiates Applicants' prerogative to claim their invention as they choose. Applicants have defined their invention to be, for example, the subject matter recited by Claim 60. If the Restriction Requirement is imposed and the subject matter of Claim 60 is dispersed to many claims, the P.T.O. would define Applicants' invention, as unambiguously prohibited in *Weber*. Further, restriction within a single claim improperly limits the scope of Applicants' invention as claimed in view of their description of the invention. Applicants have described a genus of bacterial sialyltransferases that can be used to practice the methods of the invention. Under 35 U.S.C. § 112, Applicants are entitled to patent protection commensurate with their disclosure. Accordingly, restriction within a single claim is improper as it denies Applicants the right to claim their invention as they choose.

In addition, the totality of the resulting fragmentary claims following restriction within Claim 60 would not be the equivalent of original Claim 60 as cautioned by *Weber*. If Claim 60 is internally restricted, Applicants would be forced to prosecute fragments of Claim 60, each drawn to a particular species of bacterial sialyltransferase, in a number of applications. Even if Applicant pursued this course, the scope of coverage of the resulting fragmentary claims would not be likely to be equivalent to original Claim 60. Thus, restriction within Claim 60 improperly limits the scope of Applicants' invention to methods of using individual species of bacterial sialyltransferases in view of Applicants' description of a genus of bacterial sialyltransferases that sialylate glycoproteins.

Finally, restriction within a single claim places an enormous burden on Applicants in achieving patent protection of the invention as currently claimed. If Applicants are restricted to individual species of particular bacterial sialyltransferases, Applicants would need to prosecute a vast number of applications, each directed to an individual species, to obtain equivalent coverage. It is unreasonable for the P.T.O. to require Applicants to prosecute

thousands to millions of applications when the P.T.O. has established procedures that minimize the burden on the RT.O. in examining generic claims.

Applicants respectfully submit that the proper procedure for reducing the administrative burden on the P.T.O. when examining a generic claim is Election of Species. According to this practice, Applicants elect a species upon which the generic claims read in order to facilitate examination of such claims. Where both generic and specific claims are presented in an application, election of species to facilitate the examination of the generic claims is proper. *See* M.P.E.P. § 808.01(a). Even where no specific claims are presented, election of species is proper when examination of the generic claims would require an unduly extensive or burdensome search. *See id.*

Accordingly, Applicants propose to elect a species encompassed by the generic claims to facilitate prosecution on the merits. *See id.* Should the P.T.O. conclude that an Election of Species is in fact proper, Applicants could, for example, elect the species of methods for sialylating a glycoprotein using a bacterial sialyltransferase in which the bacterial sialyltransferase is a *C. jejuni* sialyltransferase, to facilitate prosecution on the merits. Should Applicants elect this species, Applicants believe that Claims 60, 65-66, and 81-83 would read upon the elected species.

Such an election of species would reduce the administrative burden on the P.T.O. while preserving Applicants' right to claim their invention as they choose. Therefore, Applicants respectfully request that the outstanding Restriction Requirement be withdrawn.

As shown by the foregoing discussion, the Restriction Requirement imposed by the P.T.O. communication of June 18, 2004 does not comport with 35 U.S.C § 121, 37 C.F.R. § 1.141, and M.P.E.P. §§ 800 *et seq.* In accordance with the proper procedures, Applicants stand ready to elect a species to facilitate examination of the generic, subgeneric, and specific claims of the instant application. Accordingly, Applicants respectfully request reconsideration of the Restriction Requirement pursuant to 37 C.F.R. § 1.143.

Appl. No. 10/081,455
Amdt. dated July 19, 2004
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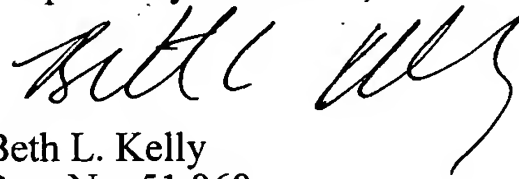
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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